Natural Products ASSOCIATION™
Promoting Natural Products for Healthy Lifestyles
Formerly NNFA

1773 T Street, N.W., Washington, DC 20009
(202) 223-0101, Fax (202) 223-0250
www.NaturalProductsAssoc.org

January 12, 2009

Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 I Street
Sacramento, CA 95812
Filed via e-mail: fkammerer@oehha.ca.gov

Re: Proposition 65 Regulatory Update Project – Regulatory Concepts for Exposure to Human and Plant Nutrients in a Human Food; Draft Initial Statement of Reasons - Title 27, California Code of Regulations: Proposed New Sections 25506 and 25507 Exposures to Human and Plant Nutrients in a Food

Dear Ms. Kammerer:

The Natural Products Association submits these comments in response to the Notice of Public Workshop dated November 3, 2008, and the Draft Initial Statement of Reasons (ISOR) dated November 20, 2008. The Natural Products Association was founded in 1936 to promote and protect the unique values and shared interests of retailers and suppliers of natural nutritional foods and natural products. The Natural Products Association is a non-profit 501 (c) (6) association whose mission is to unite a diverse membership, from the smallest health food store to the largest natural products supplier. We champion consumers' freedom of choice in our marketplace. We strengthen and safeguard retailers and suppliers. We build strong markets to fuel industry growth. We act together with uncompromising integrity, and we encourage all to reach ever higher standards of quality. We are the largest trade association in the Natural Products industry by numbers, representing over 10,000 members. Thank you very much for the opportunity to comment.

As we noted in our initial comments sent to OEHHA in May of 2008, we appreciate OEHHA's intention to ameliorate the adverse consequences of future decisions to list human or plant nutrients under Proposition 65. Per those previously cited reasons in addition to the matters cited below, the Natural Products Association must reluctantly oppose the regulatory proposal because it is unauthorized and unnecessary, and because it will subject, not only California's food and agricultural industries, but the Nation's to expensive litigation and misleading, anti-competitive warnings on healthful and nutritious foods, which concerning at any point in time, is of even greater concern given the current economic climate.

OEHHA's Draft ISOR is correct in stating, "*it is not in the interest of public health to warn the public away from foods that are beneficial to their health and safe to consume*." Nutrients that are essential to a healthy diet should not have a Proposition 65 warning. Up to now, retinol is the only chemical listed as a DART or carcinogen and that is also a beneficial nutrient. When retinol was listed, OEHHA made a decision on a case-by-case basis, similar to what is being proposed now. This again begs the question, as it was asked at the earlier hearing, whether the proposal can be substantiated by administrative law. No other rules applied after retinol was identified as a DART when levels were sufficiently excessive. Under the current regulatory scheme, when OEHHA considers other beneficial nutrients to warrant possible listing as a DART or carcinogen, it must give public notice about which

those are so that stakeholders can prepare substantive comments with full information about the chemicals in question. We believe this approach, though we are in disagreement with some of the "*scientific rules*" applied by OEHHA, is the only appropriate approach.

The Draft ISOR is incorrect when it assumes that the proposed regulation will avoid warnings on healthful foods. It is also wrong to assert that the proposal "*will not adversely affect small businesses*" and "*will not have a significant statewide adverse economic effect*" because it "*provides an affirmative defense*." I believe the testimony from the representative from the California Secretary of Agriculture at the December 12, 2008; hearing speaks to the concern of the initiative as a potential barrier to trade and having an adverse economic impact. With respect to the proposal being an affirmative defense, it is important to not that many businesses provide warnings even though they have valid, well-supported affirmative defenses to Proposition 65 actions --because those affirmative defenses, which rely on sophisticated scientific experts, can cost millions of dollars to prove in court. Many businesses choose the burden of warnings simply to avoid the greater burden of expensive litigation over their affirmative defenses. Labeling costs additionally are not economically insignificant; a recent notice from FDA to the Office of Management and Budget (OMB) indicated that a labeling change for a dietary supplement product costs approximately $ 4,000.00 per product.

The affirmative defense created by the proposed regulation is no different from the existing, essentially meaningless affirmative defenses. The proposal would require a food or dietary supplement producer to prove that the "*reasonably anticipated exposure*" to a nutrient is less than the to-be-determined amount. For plant nutrients in foods or dietary supplements, the producer must also show and that the nutrient was "*added in an amount necessary to maintain healthy plant development*." But crops are sold as commodities; the packager may have no way to trace the grower –let alone prove the condition of the grower's soil. And bounty-hunters will always find their own "experts" to argue about what amounts are "*reasonable*" or "*necessary*."

This new affirmative defense refers to the existing "*naturally occurring*" defense –which also fails to protect foods. Under the naturally-occurring exemption, a listed chemical in a food is exempt insofar as the defendant can prove that it "*did not result from any known human activity*" and that it "*was not avoidable by good agricultural or good manufacturing processe*s." Again this position has not provided a defense in the past to bounty hunters. Plant nutrients are not protected under the naturally occurring exemption, because they are added to the soil by human activity. Plant nutrients are depleted by plant growth and must be added to soil each growing season. Although the naturally-occurring exemption excludes "*mechanical preparation of the soi*l" such as plowing, it does not exclude chemical preparation of the soil by adding fertilizers or soil amendments. Under the naturally occurring regulation, listed nutrients could require warnings even if they wind up in food as a result of amending the soil with boron, gypsum or compost.

Even if natural presence in the soil can be proved, "*good agricultural processes*" are not defined. While good manufacturing practices are defined they do not appear to be recognized by OEHHA, more troubling is that Bounty-hunters are free to argue that the level of the chemical would have been lower if the grower had done more to reduce it, an argument to which there seems to be no defense. To this end, the tuna industry recently spent more than $4 million to prove affirmative defenses in a Proposition 65 trial. This is the reason Proposition 65 trials are rare: almost all defendants settle rather than risk a trial that could leave their businesses bankrupt and their reputations shattered.

The real problem is not a lack of affirmative defenses. The real problem is the proposal to list human and plant nutrients. If nutrients are listed and foods are exempted, then consumers will be misled by seeing warnings on minor exposures while the major exposure –a balanced diet—has no warning. If nutrients are listed and the exemption doesn't work, then consumers will be misled by warnings implying that a healthy diet is hazardous to their health. The only way to avoid misleading consumers is to avoid listing nutrients.

The Draft ISOR suggests that the sole alternative to the proposed regulation is the flawed proposal presented and rejected last April. In fact there is a better alternative: Don't list human and plant nutrients. Recognize that Proposition 65 was never intended to create warnings for essential nutrients. There is no mandate for listings that undermine the initiative's intended application to "*dangerous*" chemicals that are "*extremely toxic*." Human and plant nutrients are not "*dangerous chemicals*;" they are indistinguishable from the same chemicals that occur naturally, which must be replenished when depleted from the soil by normal plant growth.

The proposal anticipates that OEHHA will set an acceptable level of exposure for human and plant nutrients that is orders of magnitude higher than the statutory thousand-fold factor below the NOAEL. The Draft ISOR omits any reference to an authorizing statute. There is no reason to believe that OEHHA has authority to contradict the statutory thousand-fold factor.

Even if OEHHA had the authority to determine an acceptable exposure to human or plant nutrients, it lacks the expertise. OEHHA's expertise is not food safety and nutrition.

Listing human and plant nutrients under Proposition 65 would undermine the public health and the state's economy with misleading warnings on healthful foods. The regulatory proposal will not mitigate those effects. It is unnecessary and unauthorized.

The Natural Products Association urges OEHHA not to adopt the regulatory proposal, and not to take further action to list human or plant nutrients under Proposition 65.

Best regards,

Daniel Fabricant, Ph.D.
Vice President, Scientific & Regulatory Affairs
dfabricant@naturalproductsassoc.org